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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,636	04/01/2004	Patrick T. Petruno	10040213-1	1047

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AVAGO TECHNOLOGIES, INC.  
P.O. BOX 1920  
DENVER, CO 80201-1920

EXAMINER

YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/816,636

Applicant(s)

PETRUNO ET AL

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-12, 21-26 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) 32-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12, 21-26, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/2</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's arguments and amendments filed 1 November 2005 have been entered.

#### ***Election/Restrictions***

2. Newly submitted claims 32-36 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of group I, claims 10-12, 21-26 and 30-31 and group II, claims 32-36, are patentably distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. The invention of group I, is drawn to a test system comprising a light source, which is not required of group II. The invention of group II requires a reusable module, which is not required of the invention of group I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-36 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Status of the Claims***

3. Claim 10 is currently amended. Claims 30-36 are new. Claims 32-36 have been withdrawn. Claims 1-9, 13-20 and 27-29 are canceled. Claims 10-12, 21-26 and 30-36 are currently pending in this application.

#### ***Withdrawn Rejections***

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4. Previous rejections under 35 USC 112, second paragraph have been withdrawn in light of applicant's amendments.

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites "the first" and "the second" in lines 2 and 3 of the claim. Claim 31 recites "the test" in line 3 of the claim. There is insufficient antecedent basis for these limitations in the claims.

***Claim Rejections - 35 USC § 103***

6. Claims 10-12 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 5,837,546) in view of Straus (US 2003/0082516).

Regarding claims 10 and 23, Allen et al. teach a diagnostic system comprising: a medium containing a labeling substance capable of binding an indicator to a target analyte when a sample containing the target analyte is applied to the medium (test zone comprises labeling substance, col. 12, lines 24-38, medium is a reagent strip comprising zones, col. 10, lines 57-67; col. 11, lines 21-45); a light source for illuminating a target area on the medium (light source, col. 9, lines 39-41; col. 13, lines 38-41); and a photodetector to measure light from the test area of the medium (col. 3, lines 15-21; col. 8, lines 5-8; col. 8, lines 34-37), wherein the detector and

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medium are contained in a single-use module (col. 12, line 49-col. 13, line 17). Allen et al. fail to teach a labeling substance that binds a persistent fluorescent structure to a target analyte.

Straus teaches a medium (detection zone, par. 32) comprising a labeling substance that binds a quantum dot to a target analyte (quantum dot used as a fluorescent signal element for labeling a molecule, labeling molecules bound to cell, par. 69, 203-204), in order to achieve high signal intensities.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the labeling substance of the medium of Allen et al., a labeling substance that binds a quantum dot to a target analyte as taught by Straus, in order to provide a label with a more stable and stronger signal.

With respect to claims 11 and 12, Allen et al. teach a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the single-use module and the reusable module (single-use module, Fig. 6 and 7; reusable module outside casing, parts 62 and 64 shown in Fig. 4). Allen et al. teach the electronic components, such as the outside housing for display can be reused while the inside components are disposable, therefore the single-use module would be inserted into the reusable module for communication (col. 48-53). Furthermore, claim 12 recites the reusable module implementing a user interface, which is drawn to a method and does not appear to recite any further structural limitations, therefore a device must only be capable of performing the recited method. Since Allen et al. teach the required structural limitations, the reusable module of Allen et al. would be capable of implementing a user interface for indicating test results (housing of the photodetector and test strip 62 and 64, Fig. 4).

With respect to claims 21 and 22, Allen et al. teach a user interface comprising a display for test results (col. 3, lines 27-28) and electrical test signals (col. 3, lines 20-23 and 41-44). Regarding claim 26, Allen et al. teach a lateral flow strip for performing a binding assay (col. 11, lines 43-49), and the test area contains an immobilized substance that binds to and holds a complex including the labeling substance and the target analyte (par. 11, lines 43-48).

Regarding claims 24 and 25, Straus teaches a photodetector positioned to measure light (photodetectors used to measure properties, par. 169, 222) that has a frequency characteristic of fluorescent light resulting from the light source illuminating the quantum dot (quantum dots generate strong fluorescent signal therefore the photodetector detects light that has a frequency characteristic of fluorescent light, par. 203), in order to detect fluorescence emitted by quantum dots.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the photodetector of Straus for the photodetector of Allen et al. when quantum dots are used as the indicator of Allen et al.

Regarding claim 26, Allen et al. teach a lateral flow strip for performing a binding assay (col. 11, lines 43-49), and the test area contains an immobilized substance that binds to and holds a complex including the labeling substance and the target analyte (par. 11, lines 43-48).

7. Claims 10-12, 21-23, 26 and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 5,837,546) in view of Daniels et al. (US 2002/0004246).

Regarding claims 10 and 23, Allen et al. teach a diagnostic system comprising: a medium containing a labeling substance capable of binding an indicator to a target analyte when a sample containing the target analyte is applied to the medium (test zone comprises labeling substance,

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col. 12, lines 24-38, medium is a reagent strip comprising zones, col. 10, lines 57-67; col. 11, lines 21-45); a light source for illuminating a target area on the medium (light source, col. 9, lines 39-41; col. 13, lines 38-41); and a photodetector to measure light from the test area of the medium (col. 3, lines 15-21; col. 8, lines 5-8; col. 8, lines 34-37), wherein the detector and medium are contained in a single-use module (col. 12, line 49-col. 13, line 17). Allen et al. fail to teach a labeling substance that binds a persistent fluorescent structure to a target analyte.

Daniels et al. teach a labeling substance that comprises a quantum dot, which is a persistent fluorescent structure, the labeling structure being capable of binding the quantum dot to a target analyte (semiconductor nanocrystal is a quantum dot, par. 79; quantum dot is detection reagent, par. 111; quantum dot labels analyte, par. 137), in order to provide a detection reagent that is capable of giving quantitative results for multiple analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the labeling substance of the medium of Allen et al., a labeling substance that binds a quantum dot to a target analyte as taught by Daniels et al., in order to provide an indicator reagent unique tags for detection of biological molecules that further provide the ability to observe discrete optical transitions. The tunable emission properties allow multiple analyte detection to be carried out in one test strip and greater sensitivity and dynamic range can be achieved relative to conventional detection reagents. Use of quantum dots in a test strip is also advantageous because a system can be designed to minimize substrate autofluorescence by selecting well-separated excitation and emission wavelengths.

With respect to claims 11 and 12, Allen et al. teach a reusable module having a receptacle into which the single-use module can be inserted for communication of test signals between the

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single-use module and the reusable module (single-use module, Fig. 6 and 7; reusable module outside casing, parts 62 and 64 shown in Fig. 4). Allen et al. teach the electronic components, such as the outside housing for display can be reused while the inside components are disposable, therefore the single-use module would be inserted into the reusable module for communication (col. 48-53). Furthermore, claim 12 recites the reusable module implementing a user interface, which is drawn to a method and does not appear to recite any further structural limitations, therefore a device must only be capable of performing the recited method. Since Allen et al. teach the required structural limitations, the reusable module of Allen et al. would be capable of implementing a user interface for indicating test results (housing of the photodetector and test strip 62 and 64, Fig. 4).

With respect to claims 21 and 22, Allen et al. teach a user interface comprising a display for test results (col. 3, lines 27-28) and electrical test signals (col. 3, lines 20-23 and 41-44). Regarding claim 26, Allen et al. teach a lateral flow strip for performing a binding assay (col. 11, lines 43-49), and the test area contains an immobilized substance that binds to and holds a complex including the labeling substance and the target analyte (par. 11, lines 43-48).

Regarding claim 26, Allen et al. teach a lateral flow strip for performing a binding assay (col. 11, lines 43-49), and the test area contains an immobilized substance that binds to and holds a complex including the labeling substance and the target analyte (par. 11, lines 43-48).

With respect to claims 30 and 31, Allen et al. teach a preferred embodiment providing a multi-assay for determining the presence of a plurality of selected analyte in a sample detected with a plurality of reagents (col. 3, lines 29-39), wherein a first and second analyte are assayed



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(col. 3, lines 52-56) and the separate sampling area for each analyte (col. 3, line 65-col. 4, line 19; col. 10, lines 52-59), but fail to teach a first and second type of quantum dot.

Daniels et al. teach the labeling substance comprising a first type of quantum dot that emits light having a first frequency; and a second type of quantum dot that emits light having the second frequency (par. 207 and 225), in order to provide a distinct emission characteristic for multiple analyte.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use as the detection reagents for multiple analyte in the test strip of Allen et al., a first and second type of quantum dot that emit light at a first and second frequency, respectively, as taught by Daniels et al., in order to provide an indicator with greater sensitivity and dynamic range for detecting multiple analyte in a sample on the same test strip.

Daniels et al. teach the first type of quantum dot attached to a substance that binds to the target analyte and to the test area (detection complex comprising target analyte and quantum dot, a separate test region comprising a specific capture reagent exists to capture each detection complex therefore the first type of quantum dot is attached to a substance that binds the target analyte and the test region, par. 223); and the second type of quantum dot attached to a substance that binds to a control area of the medium (control region captures any excess detection complex, therefore, when multiple analyte are tested, a second quantum dot is used as indicated in par. 225, and a second quantum dot that is attached to a second target analyte would bind to the control area, par. 223-225 and par. 207).

*Response to Arguments*

8. Applicant's arguments filed 1 November 2005 have been fully considered but they are not persuasive. On pages 5-6 of applicant's response, applicant argues that Allen does not disclose or suggest use of a labeling substance containing a persistent fluorescent structure. However, in response to applicant's argument, the reference of Allen is not relied upon for a labeling substance containing a persistent fluorescent structure. The reference of Straus teaches a persistent fluorescent structure and the incorporation of the quantum dot of Straus in the reference of Allen would have been obvious to one having ordinary skill in the art as described above.

On page 6 of applicant's response, applicant argues that Straus is directed to detecting replication of cells and does not disclose a diagnostic system and the detection system uses or requires growth of microbe colonies. However, in response to applicant's arguments, the reference of Straus is relied upon only for the use of quantum dots as an indicator or label for a target analyte and is not relied upon for being a rapid diagnostic system. Furthermore, it would have been obvious to one having ordinary skill in the art to use as the indicator of Allen, the quantum dots to label target analyte as taught by Straus, in order to provide an indicator with a signal that is stronger and more stable than other label reagents known in the art.

Regarding claim 11, on pages 6-7 of applicant's response, applicant argues that Allen discloses an embodiment with a re-usable portion, which includes electronics, and the single-use portion of Allen includes test strips, and therefore the photodetector is contained in the re-usable unit and the test strip is the single-use component. However, in response to applicant's argument, all embodiments of the invention must be considered. As applicant describes, Allen

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also teaches an embodiment wherein the test system, including the photodetector and test strip, are contained in a single-use test system, as indicated by the single, disposable unit described at col. 7, lines 45-56. Although Allen describes the reagent strip may be replaced once or several times such that the electronics component is re-used, this is merely one embodiment of the invention and instant claim 11 does not exclude possible reuse of electronics.

9. A new rejections under 35 USC 103(a) over Allen in view of Daniels due to applicant's amendment adding new claims 30 and 31.

### *Conclusion*

No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu  
Patent Examiner  
Art Unit 1641



**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

01/17/06